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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,416	11/05/2001	Russell Phillips	R-236	1745

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EXAMINER
BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,416	PHILLIPS ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a targeting construct and a method of producing the gene-targeting construct, classified in class 536, subclass 23.1.

II. Claims 5-10, 16-21 and 23 drawn to a non-human transgenic animal comprising a disruption in a secreted protein gene, cells comprising a disruption in a secreted protein gene, and methods of making the transgenic non-human animal comprising a disruption in a secreted protein gene using the cells, and in vivo methods of using the animals identifying an agent that modulates the expression of a secreted protein gene classified in class 800, subclass 3, 8, 21, 25; class 435, subclass 455, 463, 320.1, 325; class 424, subclass 9.2.

III. Claims 11 and 12, drawn to an in vivo method of identifying an agent that modulates a secreted protein gene, classified in class 800, subclass 3.

IV. Claims 13 and 14, drawn to an in vitro method of identifying an agent that modulates a secreted protein gene using a cell comprising a disruption in a secreted protein gene, classified in class 435, subclass 4, 6.

V. Claim 15, drawn to an unknown agent that modulates the expression of a secreted protein encoding gene using a non-human transgenic animal, unclassifiable.

VI. Claim 22, drawn to methods of identifying agents that modulates expression of a secreted protein gene using a transgenic mouse comprising a disruption in a secreted protein gene, classified in class 800, subclass 3.

VII. Claims 24 and 25, drawn to methods of identifying an agent that modulates the function of a secreted protein gene using a cell comprising a secreted protein gene, classified in class 435, subclass 6.

VIII. Claim 26, drawn to an in vitro method of identifying an agent that has an effect on depression using a secreted protein, classified in class 435, subclass 4.

IX. Claim 27, drawn to an in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene, classified in class 435, subclass 6.

X. Claims 28 and 29, drawn to an in vitro method of identifying an agent that has an effect on depression using a cell over-expressing a secreted protein gene, classified in class 435, subclass 6.

XI. Claim 30, drawn to an unknown agent that has an effect on depression, unclassifiable.

XII. Claim 31-35, drawn a method of treating depression in a patient by administering an agent, classified in class 514, subclass 2.

Inventions I and II are patentably distinct. The nucleic acid construct of Invention I can be used as probe while the cells of Invention II can be used in *in vitro* assays and the transgenic non-human animal of Invention II can be used to observe a secreted protein gene function or as a model for disease or condition. The cells and animal are not necessary for the nucleic acid and the nucleic acid is not necessary for the cells or animal. The nucleic acid and the cells and animal are classified differently. The burden required to search inventions I and II together would be undue.

Inventions I and any of Inventions III-XII are mutually exclusive and independent. The nucleic acid construct of Invention I is not required for the implementation of *in vivo* methods of identifying an agent that modulates the function of a secreted protein gene of Invention III, the *in vitro* methods of identifying an agent that modulates the expression of a secreted protein gene of Invention IV, the unknown agent of Invention V, the methods of identifying agents that modulate a secreted protein expression using a transgenic mouse comprising a disruption in a secreted protein gene of Invention VI, the methods of identifying an agent that modulates a secreted protein gene function using a cell comprising a secreted protein gene of Invention VII, the in vitro method of identifying an agent that has an effect on depression using a secreted protein of Invention VIII, the in vitro method of identifying an agent that has an effect on depression using a cell expressing or overexpressing a secreted protein gene of Inventions XI or X, the unknown

agent of Invention XI and a method of treating depression in a patient of Invention XII, and vice versa. The nucleic acid of Invention I and products and methods of Inventions III-XII are classified differently. The burden required to search inventions I and any of Inventions III-XII together would be undue.

Invention II and each of Inventions III, IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic non-human animal of Invention II can be used as a model for disease or condition and the cells of Invention II can be used to produce a secreted protein *in vitro*.

Invention II and Invention V are mutually exclusive and independent. The transgenic non-human animals of Invention II are not required for the agent of Invention V, and the agent is not necessary for the transgenic non-human animals. The inventions are classified separately. The burden required to search inventions II and V together would be undue.

Invention II and any of Inventions VII-X and XII are patentably distinct. The transgenic non-human animals are not necessary for the methods of any of Inventions VII-X and XII and the methods of Inventions VII-X and XII are not necessary for the transgenic non-human animals of Invention II. Invention II and Inventions VII-X and XII are classified separately. The burden required to search Invention II and any of Inventions VII-X and XII together would be undue.

Invention II and Invention XI are mutually exclusive and independent. The transgenic non-human animals of Invention II are not required for the agent of Invention XI, and the agent

is not necessary for the transgenic non-human animals. The inventions are classified separately. The burden required to search inventions II and XI together would be undue.

Invention III and each of Inventions IV, VI-X and XII are mutually exclusive and independent. The in vivo methods of identifying an agent that modulates the function of a secreted protein gene of Invention III are not required for the implementation of the in vitro methods of identifying an agent that modulates the expression of a secreted protein gene of Invention IV, the methods of identifying agents that modulate a secreted protein expression using a transgenic mouse comprising a disruption in a secreted protein gene of Invention VI, the methods of identifying an agent that modulates a secreted protein gene function using a cell comprising a secreted protein gene of Invention VII, the in vitro method of identifying an agent that has an effect on depression using a secreted protein of Invention VIII, the in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene of Invention IX or X, and a method of treating depression in a patient of Invention XII, and vice versa. Each of the methods requires a separate and materially different protocol. The methods of Invention III and products and methods of Inventions IV-XII are classified differently. The burden required to search Inventions III and any of Inventions IV, VI-X and XII together would be undue.

Inventions III, IV, VI-X or XII and Invention V are patentably distinct because the agent of Invention V can be identified using different methods. The methods of Inventions III, IV, VI-X or XII are not required for the agent and the agent is not required for the methods. The methods and the agent are classified differently. The burden required to search any of Inventions III. IV. VI-X or XII and Invention V together would be undue.

Inventions III, IV, VI-X or XII and Invention XI are patentably distinct because the agent of Invention XI can be identified using different methods. The methods of Inventions III, IV, VI-X or XII are not required for the agent and the agent is not required for the methods. The methods and the agent are classified differently. The burden required to search any of Inventions III, IV, VI-X or XII and Invention XI together would be undue.

Invention IV and each of Inventions VI-X or XII are mutually exclusive and independent. The in vitro methods of identifying an agent that modulates the expression of a secreted protein gene of Invention IV is not required for the methods of identifying agents that modulate a secreted protein expression using a transgenic mouse comprising a disruption in a secreted protein gene of Invention VI, the methods of identifying an agent that modulates a secreted protein gene function using a cell comprising a secreted protein gene of Invention VII, the in vitro method of identifying an agent that has an effect on depression using a secreted protein of Invention VIII, the in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene of Invention IX or X, and a method of treating depression in a patient of Invention XII, and vice versa. Each of the methods requires a separate and materially different protocol. Furthermore, each of the methods requires a separate and materially different protocol. The methods of Invention IV and products and methods of Inventions VI-X and XII are classified differently. The burden required to search Inventions IV and any of Inventions VI-X or XII together would be undue.

Inventions V and XI are patentably distinct because, the agent of Invention V can be used to modulate a secreted protein while the agent of Invention XI can be used to treat depression.

The protocols and reagents required for each agent and the methods are materially distinct and separate. The agent of Invention V does not require the agent of Invention XI and vice versa.

Invention VI and any of Inventions VII-X or XII are mutually exclusive and independent. The methods of identifying agents that modulate a secreted protein expression using a transgenic mouse comprising a disruption in a secreted protein gene of Invention VI are not required for the implementation of the methods of identifying an agent that modulates a secreted protein gene function using a cell comprising a secreted protein gene of Invention VII, the in vitro method of identifying an agent that has an effect on depression using a secreted protein of Invention VIII, the in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene of Invention IX or X, and a method of treating depression in a patient of Invention XII, and vice versa. Each of the methods requires a separate and materially different protocol. Furthermore, each of the methods requires a separate and materially different protocol. The methods of Invention VI and products and methods of Inventions VII-X or XII are classified differently. The burden required to search Invention VI and any of Inventions VII-X or XII together would be undue.

Invention VII and any of Inventions VIII-X or XII are mutually exclusive and independent. The methods of identifying an agent that modulates a secreted protein gene function using a cell comprising a secreted protein gene of Invention VII are not required for the implementation the in vitro method of identifying an agent that has an effect on depression using a secreted protein of Invention VIII, the in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene of Invention IX or X, or a method of treating depression in a patient of Invention XII, and vice versa. Each of the

methods requires a separate and materially different protocol. Furthermore, each of the methods requires a separate and materially different protocol. The methods of Invention VII and products and methods of Inventions VIII-X or XII are classified differently. The burden required to search Invention VII and any of Inventions VIII-X or XII together would be undue.

The methods of each of inventions VIII-X and XII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention VIII is drawn to an in vitro method of identifying an agent that has an effect on depression using a secreted protein. Invention IX is drawn to an in vitro method of identifying an agent that has an effect on depression using a cell expressing a secreted protein gene. Invention X is drawn to an in vitro method of identifying an agent that has an effect on depression using a cell overexpressing a secreted protein gene. Invention XII is drawn to a method of treatment. Each of the methods is distinct and one is not necessary for the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

PETER PARAS
PATENT EXAMINER

Valarie Bertoglio
Examiner
Art Unit 1632